IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9064

Bartle, J. May 10, 2013

Cynthia A. Morton ("Ms. Morton" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Larry E. Morton, Ms. Morton's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In October, 2006, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Joseph S. Weinstein, M.D., F.A.C.C. Based on an echocardiogram dated May 6, 2003, Dr. Weinstein attested in Part II of Ms. Morton's Green Form that claimant suffered from moderate mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction in the range of 50% to 60%. Based on such

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3. (...continued)
contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $549,753.[4]

In the report of claimant's echocardiogram, the reviewing cardiologist, Michael A. Rubin, M.D., F.A.C.C., stated that claimant had "[m]oderate [mitral regurgitation] with regurgitant jet fraction 29%." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In January, 2007, the Trust forwarded the claim for review by Robert L. Gillespie, M.D., F.A.C.C., F.A.S.E., one of its auditing cardiologists. In audit, Dr. Gillespie concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation because her echocardiogram demonstrated only trace

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4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's findings of an abnormal left atrial dimension or a reduced ejection fraction, each of which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

mitral regurgitation.[5] In support of this conclusion, Dr. Gillespie observed:

> The Nyquist Limit was initially set correctly at 61 cm/sec in the parasternal view and in the parasternal view, the [mitral regurgitation] was trace. The technician then decreased the Nyquist Limit to 42 cm/sec in the apical views which over estimated [the] [mitral regurgitation] jet. The Nyquist was never set at an appropriate setting in the apical views.

Based on Dr. Gillespie's finding that claimant did not have moderate mitral regurgitation, the Trust issued a post-audit determination denying Ms. Morton's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[6] In contest, claimant submitted a letter from Dr. Rubin, wherein he reaffirmed his finding that claimant's May 6, 2003 echocardiogram demonstrated moderate mitral regurgitation. Dr. Rubin explained:

> The magnitude of the mitral regurgitation demonstrated on May 6, 2003 compared to April 12, 2004 does appear, as the record shows, to be slightly worse on the first study as compared to the later study. By the

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5. As noted in the Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue, trace, trivial, or physiologic mitral regurgitation is defined as a "[n]on-sustained jet immediately (within 1cm) behind the annular plane or <+ 5% RJA/LAA."

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Morton's claim.

> Singh classification using regurgitant fraction for determining magnitude of regurgitant leaks, both mitral valve calculations were in the moderate severity range. This classification is the one utilized in the Phen-Fen class action lawsuit. By more global parameters of assessment, both mitral regurgitant leaks appeared to be in the mild range. I do not dispute the magnitude of regurgitation in either study as measured by either technique and I do believe that these are correct assessments of both of these echocardiograms notwithstanding the above parenthetical statements that I have just made regarding these two studies.

In addition, Ms. Morton argued that the auditing cardiologist interpreted the level of regurgitation based on the parasternal, rather than apical, views. Claimant also asserted that the auditing cardiologist did not properly apply the reasonable medical basis standard because he substituted his personal opinion for that of the attesting physician. Ms. Morton also contended that the concept of inter-reader variability provided a reasonable medical basis for the attesting physician's representation of moderate mitral regurgitation. Finally, she argued that there was a reasonable medical basis for her claim because she received a Cash Benefit based on her May 6, 2003 echocardiogram, which was performed as part of the Trust's Screening Program.[7]

The Trust then issued a final post-audit determination, again denying Ms. Morton's claim. Claimant disputed this final

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7. See Settlement Agreement § IV.A.1.a. (Screening Program established under the Settlement Agreement).

determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807; Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Morton's claim should be paid. On October 25, 2007, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 7488 (Oct. 25, 2007).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on May 28, 2008. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[8] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical

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8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Morton reasserts the arguments she raised in contest. In addition, she contends that the representation of an attesting physician must be accepted unless it is "irrational, foolish, senseless, etc. from any medical perspective." She also asserts that several echocardiograms and a catheterization performed subsequent to her May 6, 2003 echocardiogram corroborate her attesting physician's and reviewing cardiologist's determinations of moderate mitral regurgitation.

In response, the Trust asserts that claimant did not rebut Dr. Gillespie's findings at audit. In addition, the Trust argues that the auditing cardiologist did not substitute his

personal opinion for that of Dr. Weinstein and contends that the concept of inter-reader variability does not establish a reasonable medical basis for Dr. Weinstein's representation because Dr. Gillespie specifically found that the Nyquist setting on claimant's echocardiogram was too low.[9]

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation. Specifically, Dr. Vigilante observed:

> I reviewed the tape of the Claimant's May 6, 2003 echocardiogram.... The usual echocardiographic views were obtained. The echo gain was appropriate. However, the study was not performed in accordance with the usual standards of care. The initial Nyquist limit in the parasternal long-axis view as appropriate at 61 cm per second at a depth of 17 cm. This setting produced appropriate color Doppler signals. However, the Nyquist limit was then reduced suddenly to 49 cm per second at a depth of 17 cm causing color artifact. In the apical views, an inappropriately low Nyquist limit of 42 cm per second was used at a depth of 20 cm. This low Nyquist limit was noted in both the apical four chamber and apical two chamber views. This low Nyquist limit caused significant color artifact. The color gain setting was too high with inappropriate manifestation of low velocity and non-mitral regurgitant flow.

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9. The Trust also argues that the letter from Dr. Rubin is not permitted by the Audit Rules because it is unverified. We disagree. As we previously have stated, "While the Audit Rules allow for the submission of verified expert opinions, it does not preclude the submission of expert opinions that are not verified." PTO No. 7402 at 8 n.9 (Aug. 30, 2007) (citing Audit Rule 18(b)).

.... Visually, trace mitral regurgitation was suggested in the parasternal long-axis view and trace to mild mitral regurgitation was suggested in the apical views. I digitized those cardiac cycles in the apical four and two chamber views in which the mitral regurgitant jet was best evaluated. I then digitally traced and calculated the RJA and LAA. I was able to accurately determine the mitral regurgitant jet area in the apical views during the mid portion of systole in spite of color artifact from an inappropriately low Nyquist limit and excessive color gain. In the apical four chamber view, the largest representative RJA was 1.8 cm2. I determined that the LAA was 23.3 cm2. Therefore, the largest representative RJA/LAA ratio was less than 8%. The sonographer determined an RJA of 3.05 cm2 in the apical four chamber view. This measurement was taken in early systole and was a reflection of backflow and not mitral regurgitation. The sonographer obtained an LAA of 22.5 cm2 in the apical four chamber view. This determination missed part of the back of the left atrium. The correct LAA in the apical four chamber view is 23.3 cm2. In the apical two chamber view, the largest representative RJA was 1.2 cm2. The LAA in the apical two chamber view was 22.3 cm2. Therefore, the largest representative RJA/LAA ratio in the apical two chamber view was 5%. The sonographer determined an RJA of 5.26 cm2 in the apical two chamber view. However, this supposed RJA was artifact and not true regurgitant flow. The sonographer determined an LAA of 21.8 cm2 in the apical two chamber view. This determination was similar to my LAA measurement of 22.3 cm2. This study demonstrated no RJA/LAA ratios that came close to approaching 20%. Therefore, the entire study was diagnostic of mild mitral regurgitation.

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... [T]here is no reasonable medical basis for the Attesting Physician's answer to, Green Form Question C.3.a. That is, the

> study of May 6, 2003 demonstrated mild mitral regurgitation with comments as above. An echocardiographer could not reasonably conclude that moderate mitral regurgitation was present on this study even taking into account inter-reader variability.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. As an initial matter, we disagree with Ms. Morton that Dr. Rubin's statement provides a reasonable medical basis for Dr. Weinstein's representation of moderate mitral regurgitation. We are required to apply the standards delineated in the Settlement Agreement and Audit Rules. The context of those two documents leads us to interpret the "reasonable medical basis" standard as more stringent than claimant contends. For example, as we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002).

Here, Dr. Gillespie reviewed claimant's echocardiogram and determined that the mitral regurgitation jet in the apical

views was overestimated because the Nyquist limit was too low.[10] Dr. Vigilante also determined that the Nyquist limit on claimant's echocardiogram was too low. Specifically, Dr. Vigilante observed, "In the apical views, an inappropriately low Nyquist limit of 42 cm per second was used at a depth of 20 cm. This low Nyquist limit was noted in both the apical four chamber and apical two chamber views. This low Nyquist limit caused significant color artifact." Although claimant submitted the statement of Dr. Rubin, he did not refute the specific finding that claimant's echocardiogram had inappropriately low Nyquist settings. Instead, he merely reaffirmed his determination of moderate mitral regurgitation.[11] In addition, Dr. Vigilante concluded that "[t]he color gain setting was too high with inappropriate manifestation of low velocity and non-mitral regurgitant flow."[12] Finally, Dr. Vigilante determined

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10. For this reason, we reject Ms. Morton's argument that Dr. Gillespie did not determine her level of mitral regurgitation in an apical view because he opined that her left atrial supero-inferior dimension was not evaluable in the apical four chamber view. We also reject claimant's arguments that Dr. Gillespie did not interpret the level of regurgitation based on the apical views, that Dr. Gillespie did not properly apply the reasonable medical basis standard, and that Dr. Gillespie substituted his own opinion for that of the attesting physician.

11. We also reject claimant's argument that several subsequent echocardiograms and a catheterization establish a reasonable medical basis for Dr. Weinstein's representation, based on the May 6, 2003 echocardiogram, that Ms. Morton had moderate mitral regurgitation.

12. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

that the measurement of claimant's RJA taken by the sonographer in the apical four chamber view "was taken in early systole and was a reflection of backflow and not mitral regurgitation," that the measurement of claimant's RJA taken by the sonographer in the apical two chamber view "was artifact and not true mitral regurgitant flow," and that the measurement of claimant's LAA taken by the sonographer in the apical four chamber view "missed part of the back of the left atrium." Such unacceptable practices by claimant's physician cannot provide a reasonable medical basis for the resulting diagnosis and Green Form representation of moderate mitral regurgitation. To conclude otherwise would allow claimants who do not have moderate or greater mitral regurgitation to receive Matrix Benefits, contrary to the intent of the Settlement Agreement.

Furthermore, claimant's reliance on inter-reader variability to establish a reasonable medical basis for the attesting physician's representation that she had moderate mitral regurgitation is misplaced. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's finding cannot be medically reasonable where the auditing cardiologist and the Technical Advisor concluded and claimant did not adequately dispute that Ms. Morton's echocardiogram demonstrated at most mild mitral regurgitation. Adopting claimant's argument regarding inter-reader variability would allow a claimant who did

not have the requisite level of regurgitation to recover benefits and would render meaningless this critical provision of the Settlement Agreement.[13]

Finally, there is no validity to claimant's argument that there is a reasonable medical basis for Dr. Weinstein's representation of moderate mitral regurgitation because Ms. Morton's May 6, 2003 echocardiogram was performed as part of the Trust's Screening Program. The Settlement Agreement clearly provides that the sole benefit that an eligible class member is entitled to receive based on an echocardiogram performed in the Screening Program is a limited amount of medical services or a limited cash payment:

> All Diet Drug Recipients in Subclass 2(b) and those Diet Drug Recipients in Subclass 1(b) who have been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period, will be entitled to receive, at the Class Member's election, either (i) valve-related medical services up to $10,000 in value to be provided by the Trust; or (ii) $6,000 in cash.

See Settlement Agreement § IV.A.1.c. Thus, by the plain terms of the Settlement Agreement, a Screening Program echocardiogram does not automatically entitle a claimant to Matrix Benefits.

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13. Moreover, the Technical Advisor took into account the concept of inter-reader variability as reflected in his statement, "An echocardiographer could not reasonably conclude that moderate mitral regurgitation was present on this study even taking into account inter-reader variability."

Indeed, this conclusion is confirmed by the Settlement Agreement provisions concerning claimants eligible for Matrix Benefits. Specifically, claimants receiving a diagnosis of FDA Positive or mild mitral regurgitation merely become eligible to seek Matrix Benefits. See id. § IV.B.1. Further, adopting claimant's position would be inconsistent with Section VI.E. of the Settlement Agreement, which governs the audit of claims for Matrix Benefits, as well as this court's decision in PTO No. 2662 (Nov. 26, 2002), which mandates a 100% audit for all claims for Matrix Benefits. As nothing in the Settlement Agreement supports the conclusion that a favorable Screening Program echocardiogram for purposes of Fund A Benefits results in an immediate entitlement to Matrix Benefits, we decline claimant's request to interpret the Settlement Agreement in this fashion.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Morton's claim for Matrix Benefits and the related derivative claim submitted by her spouse.